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MONSANTO COMPANY
LAWRENCE M LAVIN JR
800 N LINDBERGH BOULEVARD
MAILZONE N2NB
ST LOUIS, MO 63167

EXAMINER	
KIM, YOUNG J	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/394,745
Filing Date: September 15, 1999
Appellant(s): FISHER ET AL.

Thomas E. Kelly
David R. Marsh
Holly Logue Prutz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on June 30, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

While the appellant's statement of the issues in the brief is correct, further explanation is necessary. Appellant's statement with regard to the issues in the instant Supplemental Brief is ***drawn only to the restriction requirement***, wherein Appellants state that, "the demand to select a single combination of nucleotides for examination" (as set forth in the Restriction Requirement) "and the subsequent acts of the Office, however, denominated, constitutes a ***rejection***; and that rejection has now been twice made, thereby being ripe for appeal." (page 2, Supplemental Brief)

The restriction requirement, upon further consultation and consideration, has been ***withdrawn***, rendering Appellants' arguments made herein (Supplemental Brief received on June

20, 2003) moot. It should be noted that the resulting combination of the nucleic acids, includes a novel SEQ ID Number – SEQ ID NO: 5893 (indicated in Office Action mailed on March 18, 2002) – resulting in a novel combination of nucleic acids.

Hence, the issues remaining in the instant application are those which were raised in the Appeal Brief received on March 13, 2003 and answered to in the Examiner Answer mailed on May 23, 2003 – that is, whether the claimed combination of nucleic acids, otherwise novel, meets the requirements under 35 U.S.C. § 101; 35 U.S.C. § 112, first paragraph – enablement; and 35 U.S.C. § 112, first paragraph – written description.

Each of the above issues are addressed below.

(7) Grouping of Claims

The Supplemental Brief contains a statement which appears to be drawn to the grouping of the claims.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 8-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either specific, substantial, or a well established utility.

The claimed subject matter of claims 8-11 are not supported by a specific, substantial, or a well established utility because the disclosed uses are applicable to microarrays in general.

Further characterization of the microarray would be required to identify or reasonably confirm a "real world" use. There does not exist an adequate nexus between the evidence of record and the asserted properties of the claimed nucleic acid molecules which make up the microarray.

The claims are drawn to a microarray comprised of nucleic acid molecules, at least 10% of which are selected from a Markush Group listing of SEQ ID Numbers, all of which are derived from maize plants (page 1, line 8; page 9, line 25).

The specification identifies these SEQ ID Numbers as varying in length, but no open reading frame, start/stop codons, or encoded protein is identified in the specification and sequence listing of the SEQ ID Numbers.

General uses of a microarray comprising nucleic acid molecules set forth in the specification as filed, include screening for biological molecules, expression profiling (pages 13 and 42-43), and identifying polymorphisms (page 12, lines 15-20). None of these are considered to be specific and substantial in view of the limited information provided in the specification. No traits are attributed to the combination of the recited SEQ ID Numbers. No complete gene is disclosed nor DNA maps/chromosomal location identified. No polymorphisms are identified within the claimed nucleic acids. The specification simply fails to disclose that any of the SEQ ID Numbers contain any polymorphism. Even if *arguendo*, such polymorphisms were disclosed, a disclosure of what immediately applicable information the presence of the absence of such polymorphisms would provide to a skilled practitioner would be required to which the specification does not provide. Claims 8-11 are drawn to a microarray comprising nucleic acid molecules, the nucleic acid molecules of which are at least 250 residues in length and complementary to nucleic acid molecules represented by their SEQ ID Numbers.

Further research and experimentation would be required to identify a full length sequence that *comprise* the claimed SEQ ID Numbers. Further research and experimentation would also be required to determine any associated traits and/or function(s) encoded. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context of use.

These uses require that the nucleic acid molecules be usable as a laboratory reagent. Laboratory reagents must be sufficiently characterized and their properties understood to be used in these types of methods. In the absence of such characterization, no meaningful information is provided. The nucleic acid molecules which make up the claimed microarrays are starting materials for further research and not research tools.

Claims 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 8-11 are drawn to a microarray comprising nucleic acid molecules, derived from maize plants, the nucleic acid molecules of which are at least 250 residues in length and complementary to a molecule *comprising* the nucleic acid molecules represented by their SEQ ID Numbers.

The SEQ ID Numbers recited in the Markush group vary in their length, but no open reading frame, start/stop codons, or encoded protein is identified in the specification for these SEQ ID Numbers. As such, the claims read on a microarray comprising nucleic acid molecules, each of which have a complete open reading frame. The specification lacks such disclosure.

The use of the term, "comprising" is interpreted to encompass nucleic acid molecules with a complete open reading frame, which have not been disclosed or identified. The specification described only the recited SEQ ID Numbers and no longer sequences containing them. One can only envision the particular polynucleotide with the disclosed sequence and cannot envision polynucleotide with a larger sequence in which the claimed polynucleotide(s) with the recited SEQ ID Numbers are embedded.

(11) Response to Argument

Appellants' arguments are addressed in the order presented.

The "Brief" herein, refers to the Brief received on March 13, 2003).

Sections 8A and 8B

Appellants assert that the claimed invention (claims 8-11) meets the utility and enablement requirements because they have disclosed microarrays comprising nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, *e.g.*, the ability to efficiently analyze large amounts of nucleic acid molecules for specific nucleotide sequence or sequences" (page 3, Brief). The claimed microarray does not provide any specific benefit to the public *in their current form* but provides only a starting point from which to conduct further research to arrive at an immediately usable form and whether such usable form would provide any benefit to the public. Appellants also assert that the specification has

provided an adequate description for microarrays that are comprised on nucleic acid molecules comprising a combination of SEQ ID Numbers, because they have disclosed common structure features, that is, the sequences of the SEQ ID Numbers. To the contrary, the structure of the SEQ ID Numbers do not provide an adequate description for microarrays that are comprised of nucleic acid molecules of full-open reading frames. Neither the structural nor functional properties for any gene (including introns and other non-coding sequences) comprising the SEQ ID Numbers are disclosed in the specification.

Although "[t]he threshold of utility is not high" "[a]n invention is [to be] 'useful' under section 101 if it is capable of providing some identifiable benefit," the word "useful" is to be understood with the *proviso* that the benefit be "identifiable" in the original disclosure either as a specific assertion or being readily apparent from the disclosure (*i.e.,* well established). The invention must also have, "specific, *i.e.,* not vague or unknown benefit" and "must provide a real world, *i.e.,* practical or substantial, benefit." The instant application has not met this burden.

It is noted that the brief states in the footnote 1 on page 5 that it "is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed microarrays." The brief does not dispute that no complete open reading frame (ORF), no encoded protein, nor any biological activity for the encoded protein has been disclosed for the array of nucleic acid molecules of the recited SEQ ID Numbers. Thus the claimed nucleic acids are admitted as having no known utility.

Appellants argue that the claimed nucleic acid molecules can be used for screening for biological molecules, and as hybridization probes for expression profiling which is analogous to

cell-based assay as discussed in MPEP 2107. Although any nucleic acid molecule can be used in a screening assay, without a substantial utility (or immediately apparent applicability), one skilled in the art would not know what do to with the result of such screening assay. Thus Appellants arguments are clearly not relevant to the claimed invention. Additionally, the cell-based assay as defined by MPEP 2107 states that "[a]n assay that measures the presence of a material which has a stated **correlation to a predisposition to the onset of a particular disease condition would also define** a 'real world' context of use in identifying potential candidates for preventive measures or further monitoring." The instant **application does not show any correlation** of the SEQ ID Numbers to any disease condition. It is noted that this section of MPEP further states:

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm that a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed produce itself or the mechanisms in which the material is involved;

(B) A method of treating an unspecified disease or condition;

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;

(D) A method of making a material that itself has not specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

All of these situations more closely match Appellants' disclosed and argued uses. None of these examples are considered to define substantial utility required by 35 U.S.C. 101.

Appellants cite patent (U.S. 5,445,934) which claimed an array of oligonucleotides without specific sequences. Appellants confuse the patentability of a general microarray versus the microarray of the instant application. The '934 patent is drawn to a microarray comprising a plurality of oligonucleotides (not specific sequences) and patented by its utility for being able to analyze a plurality of nucleic acid samples simultaneously (including being able to analyze binding affinities). This is a practical and immediately apparent utility. However, the utility of the present microarray is directly dependent upon the nucleic acid molecules which the microarray comprises. Because the nucleic acid molecules which make up the claimed microarray require further experimentation to identify an immediately apparent utility, the microarray as a whole lacks utility that is substantial.

Appellants' own example of expression profiling demonstrates that the claimed microarray does not have an immediately apparent utility. A skilled practitioner would not be able to recognize what immediate benefit he/she would glean from using the claimed microarray comprising SEQ ID Number 5776 versus a microarray comprising SEQ ID Number 5782 because the nucleic acid defined by these SEQ ID Numbers have not been characterized. The specification does not give any guidance in why the skilled artisan should use a microarray comprising, for example, SEQ ID Number 5782 over a microarray comprising SEQ ID Number 5776. Therefore, the skilled artisan ***would be forced to conduct further research,*** such as differential expression analysis (*i.e.,* using sample from a plant exhibiting certain traits versus a control to generate their expression profiles) using the microarrays to determine whether or not

the nucleic acid molecules of the microarrays are differentially expressed. If, for example, SEQ ID Number 5782 was differentially expressed, then the skilled artisan would be able to arrive at a conclusion that a microarray comprising the nucleic acid molecule of this SEQ ID Number would have an immediate benefit in screening for that trait, except that the trait is not disclosed in the application. The specification provides only an invitation to further experiment to arrive at such immediately apparent utility and not a conclusion.

At page 7, line 3 of the Brief, Appellants argue that the use of the claimed microarrays for screening large populations of nucleic acids is analogous to a microscrope.

A microscope is useful in determining the structure of *any* sample of interest at the macroscopic, microscopic, or molecular level, depending on the type of microscope. For example, an artisan would be able to use a microscope to detect harmful microscopic agents that are known to exist. For the instant application, the specification does not identify what immediate benefit could be identified from using the claimed microarray.

At page 7 of the Brief, Appellants state that the use of the claimed microarrays to analyze large quantities of nucleic acid molecules is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of gas.

However, the gas chromatograph example set forth by Appellants, particularly as discussed in Footnote 4 on page 8, is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated, and calibrated to ensure accurate results. Those skilled in the art use gas chromatographs to analyze both known and unknown compounds. When the compound is unknown, the results obtained are compared to results for known compounds, e.g., standards.

Appellants even indicate why an artisan would even use the chromatograph to look for chlorine in a compound (page 8, Brief):

"The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine present, therefore the **catalyst will not be destroyed**)," (emphasis added)

Such reason arises from an immediate benefit for using the chromatograph in identifying such agents.

The claimed microarrays, however, lack this immediate benefit because the claimed microarrays were not designed for any particular purpose. Appellants merely isolated the nucleic acids and immobilized them on the microarrays' substrate. Appellants have not tested, evaluated, or calibrated the claimed microarrays for any particular use. Therefore, an expression profiling assay using the claimed microarray would not have any meaning absent some correlation to an immediate benefit. An artisan would not know why a particular microarray comprising the claimed set of nucleic acid molecules should be used in a hybridization assay over another microarray comprising an entirely different set of nucleic acid molecules derived from maize plants. Therefore, an artisan would not know, previous to further experimentation, how to use the claimed microarray for a substantial use (i.e., what meaning could be derived from using the claimed microarray).

Appellants appear to argue that the claimed microarray is a ***research tool,*** such as a gas chromatograph, and therefore have a clear, specific and unquestionable utility (page 7, Brief).

MPEP 2107 in discussing research tools sets for the following:

Some confusion can result when one attempts to label certain types of inventions as not

being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is invention to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific, and unquestionable utility (e.g., they are useful in analyzing compounds). ***An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense.*** Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. **Labels such as "research tools," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention**.

In short, a blind statement saying that an invention is a research tool would not necessarily give utility to the invention absent some specific and substantial utility. The claimed microarrays lack this substantial utility.

Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, Appellants mischaracterize the finding in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to

establish utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the claims and instant specification.

Appellants also state that the claimed microarrays allow "one of ordinary skill in the art to design or customize a particular microarray ***tailored*** to the specific ***requirements*** of the artisan himself." (emphasis added) The process of tailoring the microarray would require the knowledge of what the microarray is useful for. For example, if certain nucleic acid molecules were disclosed as being differentially expressed in herbicide-resistant plants, then a skilled artisan would be able to ***tailor*** the microarray to include such nucleic acid molecules for the immediate benefit of screening for plants with resistance to herbicides. Similarly, if certain nucleic acid molecules were disclosed as being differentially expressed in plants of a particular trait, the skilled artisan would be able to customize/tailor the microarray to include such nucleic acid molecules for assaying for the particular in a given sample. However, the specification lacks this information. Therefore, the skilled artisan would not be able to ***tailor*** the microarray for their specific ***requirements***, demonstrating that the microarray comprising the claimed nucleic acid molecules lacks substantial utility.

Appellants also cite *Nelson v. Bowler,* 206 USPQ 881 (CCPA, 1980) in arguing that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use," (page 11). This argument is not found persuasive because the fact patterns governing this decision and the instant situation are not analogous.

In *Nelson v. Bowler*, the utility of the compound was held to be substantial because the compound was a 16-phenoxy-substituted prostaglandins (PG's), a compound structurally similar to naturally-occurring prostaglandins which had an alleged effect in smooth muscle stimulation

and blood pressure modulation, such as labor induction or abortion (page 883). Examples of immediate benefits were disclosed as being stimulating uterine smooth muscle for labor induction or abortion, and modification of blood pressure for treating either shock or hypertension. Evidence of the above utility were demonstrated in BP (*in vivo* blood pressure) and GC-SMS (*in vitro* gerbil colon smooth muscle stimulation) experiments.

In short, based on the fact patterns of *Nelson v. Bowler*, one skilled in the art would have known what immediate benefit would have been gleaned from the use of the claimed compound. The disclosure and the examples clearly show that the compound would have had an immediate benefit in modifying blood pressure or labor related issues.

The fact pattern of the present application is not the same. The present application claims a microarray comprising nucleic acid molecules of different SEQ ID Numbers, all of which are derived from maize plants. None of the nucleic acid molecules have any information other than that they were derived from maize plants. Although Appellants attempt to attribute utility by listing of general utilities such as hybridization, expression profiling, mutation analysis, etc., Appellants fail to provide a substantial utility of the nucleic acid molecules on the microarray, thereby failing to give substantial utility to the claimed microarray. The present specification only provides a starting point for one skilled in the art to further experiment to arrive at a point of immediate benefit.

"A patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." *Brenner v. Manson*, 148 USPQ 689 (1966).

Since Appellants' disclosure would not allow a skilled artisan to arrive at a "successful conclusion" of an immediate benefit to the public, but only a starting point for further "search," it

is determined that the claimed microarrays comprising the recited SEQ ID Numbers do not have substantial utility.

With respect to the "real world" value of expressed sequence tags (ESTs) in general (brief, page 12), it is asserted that there is "no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed 'real world' value to such nucleic acid molecules." It is unclear as to what evidence Appellants are alluding. The evidence supplied by Appellants shows that a multimillion-dollar industry has arisen surrounding buying and selling EST databases and clone, not that anyone in this industry has bought or sold the claimed subject matter. It is noted that simply because a product, such as an EST sequence database or clone library, is bought and sold does not mean it has patentable utility.

With respect to credibility, Appellants are reminded that in order to meet the requirement of 35 U.S.C. 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that a microarray comprised on ESTs, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

The brief does not appear to directly argue for well established utility for the claimed invention; however, the arguments concerning the commercial value of ESTs in general (brief, page 12) may implicitly be directed to a well established utility for any EST in general, and the claimed nucleic acid molecules in particular. However, such evidence is not relevant to 35 U.S.C. 101.

Section 8C

The Examiner maintains that the uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study, *e.g.,* to use in a hybridization assay such as expression profiling. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within the bounds of 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

Section 8D

The issue is whether Appellants were in possession of the genus being claimed. This genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising SEQ ID Numbers as an insert. The only nucleic acid molecules described by complete structure are those which consist of the recited SEQ ID Numbers. The only nucleic acid molecules comprising the SEQ ID Numbers described in the specification by other characteristics are generic vectors comprising the SEQ ID Numbers. While it is acknowledged that Appellants need not have described "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises the recited SEQ ID Numbers and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellants were not in

possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended language of the claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for the detection of the recited SEQ ID Numbers in a target sequence, and all disclosed uses for the claimed nucleic acid molecule are fundamentally as probes or primers, as least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

Appellants state that, "one of ordinary skill in the art has the ability to make and use the claimed microarray based on the disclosure of the present specification, as well as ***envision*** a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarray." (page 16). Appellants substantiate this statement by stating that the addition of extra nucleotides or detectable labels to the sequences present on the claimed microarray is ***readily envisioned by one of ordinary skill in the art*** upon reading the present specification" (page 17).

While it is possible for one skilled in the art to envision well known vector sequences which would flank the claimed nucleic acid molecules, or addition of extra sequences such as restriction sites, the same skilled artisan would ***not*** be able to readily envision the extra nucleotide sequences of a nucleic acid molecule comprising a full-open reading frame. Simply put, theses sequences are not known. No amount of prior art, other than the sequences themselves, would allow the skilled artisan to ***envision*** these sequences. The claims clearly embrace a microarray comprising nucleic acid molecules comprising a full-opening reading frame which the present specification fails to disclose. The basic question upon which

Appellants and the Examiner disagree is whether the disclosure of a partial sequence is sufficient to establish possession of a broad genus based solely on the description of the partial sequences, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The specification fails to provide structural and functional characteristic for nucleic acid molecules comprising full-open reading frames that would distinguish them from other members of the genus, which simply comprise the recited SEQ ID Numbers as the sole distinguishing feature.

As stated in *University of California v. Eli Lilly and Co.* at page 1404, an adequate written description of a DNA... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* At 1170, 25 USPQ2d at 1606.

That Appellants claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-285 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is

unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus...").

In the instant case, the only species specifically enumerated are the nucleic acid molecules defined by the SEQ ID Numbers. The specific embodiments that in addition to the SEQ ID Numbers include nucleic acid molecules that will allow corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that these desired subcombinations were possessed by Appellants, and thus the embracing genus was not also possessed.

For the above reasons, it is believed that the rejections should be affirmed.

Respectfully submitted,

Young J. Kim
Patent Examiner
Art Unit 1637

YOUNG J. KIM
PATENT EXAMINER

yjk
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GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferees
Gary Benzion
Deborah Reynolds
Kenneth Horlick

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600 conferee

LARRY M LAVIN JR ESQ
MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
BB4F
ST LOUIS, MO 63167

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/9/04